

# Dana Farber Cancer Research Center, Harvard Medical School

Clinical Epidemiology and Validation Center

## Objectives

We have assembled a multi-disciplinary, multi-institutional team of investigators to establish a center for the clinical validation of novel prostate cancer biomarkers at 4 institutions.

## Program Description

Investigators at Dana Farber Cancer Institute in collaboration with Beth Israel– Deaconess Medical Center, Brigham and Women's Hospital, will study alpha-methylacyl-CoA racemase (AMACR) expression in cancerous tissues, and measure auto-antibody sera of patients that had cancers exhibiting aggressive pathological features and compare these among patients with more indolent prostate cancer. The primary hypothesis is that a humoral immune response to AMACR (as a prototype of various clinical measures related to prostate cancer-associated AMACR expression), or other candidate prostate antigens, is significantly associated with presence and severity of prostate cancer, and provides an opportunity for improvements in early detection of prostate cancer. This hypothesis will be addressed through evaluation of serum collected from three complementary clinical cohorts. Each of these cohorts provides complementary strengths and limitations in evaluating three aims that together address the study hypothesis as follows:

- To compare specificity of anti-AMACR antibody to the specificity of PSA for detecting prostate cancer in a prospective case-control cohort of men undergoing prostate biopsy. 1800 biopsy cases will be enrolled for this Aim.
- To validate the accuracy of humoral responses against tissue biomarkers, including AMACR, in detecting cancers and gauging cancer severity in the Physicians' Health Study cohort, a community-based cohort of physicians with and without prostate cancer. This Aim involves the evaluation of 500 prostate cancer cases and 1500 controls.
- To evaluate whether anti-AMACR auto-antibody or other humoral responses against prostatic tissue biomarkers can distinguish aggressive prostate cancers from early cancers at lower risk for extra-prostatic spread in a cohort of men treated for prostate cancer. This Aim will evaluate 1500 prostate cancer.